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Application No.: 10/786,556
Filing Date: February 25, 2004

First Inventor: Sundaram Venkataraman, et al.

Art Unit:

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Response to the Restriction Requirement, dated November 30, 2004 Business Reply Card

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IPW

In re Patent application of:
Sundaram VENKATARAMAN et al.

Application No.: 10/786,556

Filed: February 25, 2004

For: CRYSTALLINE FORM OF

RAPEPRAZOLE SODIUM AND..

Examiner: Morris, Patricia

Art Unit: 1625

Date: December 29, 2004

Atty. Docket No.: BULK 3.0-038

Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450

RESPONSE TO THE RESTRICTION REQUIRMENT

I. This paper is in response to the Office Action mailed on November 30, 2004.

It is noted that the actual number of pending claims is larger than indicated in the Office Action.

Claims 19-25, which depend from claim 18, are grouped with claim 18.

In response, Applicants elect Group I, with traverse, for prosecution on the merits.

The reason for traversing the restriction requirement are set forth below.

Inventions I and IV are related to process of making and product made. The Examiner stated that the products as claimed can be made by materially different processes as evidenced by Applicants' own specification. The Applicants respectively disagree. The specification does not contain any information of materially different process for preparing the product of Invention I. Furthermore, in order to Examine

Invention I, the Examiner is required not only to look into class of polymorphs but also classes of process for making them anyway. Including both Invention I and IV would not increase burden to the Examiner. Thus, withdraw of the restriction requirement between Inventions I and IV is respectfully requested.

The Examiner also imposed restriction requirement between Invention I and III, which are related as product and process of use. The applicants believe that this requirement is moot since the restriction requirement between Inventions I and IV should be withdrawn. Under 37 CFR 1.141(b), a three way requirement for restriction can ONLY be made where the process of making is distinct from the product. Furthermore, "[i]f the process of making and the product are not distinct, the process of using may be joined with the claims directed to the product and the process of making the product even though the a showing of distinctness between the product and process of using the product can be made." *Id.* Since Inventions I and IV, product and process of making, are not distinct as stated above, Invention III, process of using must be joined with the process of making (Invention IV) and product made (Invention I) regardless of distinctiveness between I and III. MPEP 806.05(i) Thus, it is respectfully requested that the restriction requirement between Inventions I and III be withdrawn.

With respect to Inventions I and II, the Examiner stated that Inventions I and II are unrelated because invention I does not require an additional active ingredient for the same uses. However, the Applicants do not understand how the limitation of an additional active ingredient, which is merely an additional limitation, makes claims 14 and 15 distinct and independent especially from claims 11-13. Claims 14 and 15 as well as claims 11-13 are directed to pharmaceutical composition and only difference is the

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additional limitation of the active ingredient limitation in the formers. They all define same essential features, and the claims are just "but different definitions of the same disclosed subject matter, varying in breadth or scope of definition." MPEP 806.03. Thus, the Applicants believe that the restriction requirement between Inventions I and II is improper and thus should also be withdrawn.

With reasons stated above, it is believed that the restriction requirement between Inventions I, II, III, and IV is improperly made. Thus, withdraw of the restriction requirement is respectfully requested.

Should the Examiner have any question or comments on this response or any other matter in relation with the present application, please do not hesitate to contact the undersign attorney at the number specified below. Thanks.

Respectfully submitted,

Chang Sik Kim

W/ limited recognition.